IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE '318 PATENT INFRINGEMENT LITIGATION	)	**Civil Action No. 05-356 (SLR)** **(Consolidated)**
	)	**FILED UNDER SEAL**

DEFENDANTS' REPLY TO PLAINTIFFS' ANSWERING BRIEF IN OPPOSITION TO DEFENDANTS' MOTION TO STRIKE DR. RASKIND'S TRIAL TESTIMONY ON ENABLEMENT

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TABLE OF AUTHORITIES

FEDERAL CASES

FEDERAL STATUTES

Pursuant to the Court's August 30, 2007 ruling on Defendants' E-mail Request For Emergency Relief, Defendants submit this Rely Brief to Plaintiffs' Answering Brief in Opposition to Defendants' Motion to Strike Dr. Raskind's Trial Testimony on Enablement.

I. INTRODUCTION

Plaintiffs' response to Defendants' request to strike Dr. Raskind's testimony attempts to circumvent the established rules of this Court by mischaracterizing the disclosure in Dr. Raskind's expert report[1]. Most importantly, Plaintiffs ignore the authority of this Court to create and enforce standing orders governing the disclosure of expert testimony during trial. In fact, the rule, which is the entire basis for Defendants' request to strike, was not even cited in Plaintiffs' brief. Plaintiffs attempt to skirt this Court's rule by claiming that Defendants were not prejudiced by Dr. Raskind's disclosure of expert opinions that were outside of the scope of his expert report or that Dr. Raskind's testimony had contained this theory all along. Raskind. Tr. at 1180:2-1184:17. Neither claim is supported by the record.

Defendants first learned of Dr. Raskind's opinion that a person of ordinary skill would understand the specification of the '318 patent to teach that "galanthamine was enhancing central nicotinic function" at trial and promptly objected. Raskind Tr. 1182:12-6. It is evident that this last-minute disclosure of the *nicotinic receptor theory* was clearly an *ex post facto* an attempt to enable the patent by expanding its teachings. Plaintiffs have not identified in Dr. Raskind's expert report where he discussed that the '318 patent was enabled due to the disclosure of the *nicotinic receptor theory* espoused at trial. This tactical move by Plaintiffs was extremely prejudicial to the Defendants and in violation of this Court's own standing order governing expert

[1] While Dr. Raskind submitted three expert reports, only the second report dealt with enablement.

testimony at trial. Accordingly, Dr. Raskind's Trial Testimony on enablement should be stricken from the record.

II. ARGUMENT

A. Plaintiffs Are Bound by the Court's Standing Order Governing Expert Testimony

This Court has the authority to issue its standing order governing the disclosure of expert opinions at trial. *See* Fed. Rules Civ. P. at 83(b) [2]. Plaintiffs are silent on this well-established point. The Court's guidelines, which Plaintiffs never cited, are perfectly clear that a party cannot introduce at trial expert testimony that was not previously disclosed in an expert report:

> If a party objects on the record to an expert's testimony based on claims that the testimony falls beyond the scope of his/her expert report, such objections shall be addressed during post-trial briefing. If the Court determines that the expert's testimony was impermissibly broad, the party proffering such testimony shall be sanctioned, *inter alia*, by having to assume the costs of a new trial.

The guidelines also are perfectly clear that the proper recourse for a party who believes that the other side's expert has gone beyond the scope of his/her expert report is to object and then address the objection during post-trial briefing. Plaintiffs attempt to criticize Defendants for

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[2] "Revised Rule 37(c)(1) provides an incentive for full disclosure [of an expert's opinions in his report]; namely, that a party will not ordinarily be permitted to use on direct examination any expert testimony not so disclosed." Advisory Committee Notes to the 1993 Amendments to Fed.R.Civ.P 26(a)(2)(B). Additionally, Rule 37(c)(1), as amended in 1993, "provides a self-executing sanction for failure to make a disclosure required by Rule 26(a)." Advisory Committee Notes to the 1993 Amendments to Fed.R.Civ.P. 37(c)(1). Namely, the "automatic sanction" of exclusion of evidence, "provides a strong inducement for disclosure of material that the disclosing party would expect to use as evidence." *Id.* Given the drastic changes to Fed.R.Civ.P. 26 and 37 in the 1993 amendments, it has been held that "pre-1993 cases analyzing the sanction issue under the pre-amendment rubric retain only limited authority in this post-amendment era." *Klonoski v. Mahlab*, 156 F.3d 255, 269 n. 5 (1st Cir. 1998).

not asking for a recess in order to address Dr. Raskind's nicotinic receptor theory. (Pls. Br.[3] at 7). However, such a recess would have been contrary to this Court's guidelines for resolving a dispute on the scope of expert testimony, and disrupted the trial.[4] Thus, Defendants cannot be faulted for following the Court's guidelines.

B. Dr. Raskind's Nicotinic Receptor Theory was Outside of the Scope of the Opinions Espoused in his Expert Report

Plaintiffs' claim that Defendants merely complain about the level of detail in the enablement theory disclosed in Dr. Raskind's report is wrong. (Pls' Br. at 3). Rather, Defendants assert that Dr. Raskind *never* disclosed an enablement theory based on the nicotinic receptor in his report. Plaintiffs apparently came up with this theory at trial. The sum total of Dr. Raskind's enablement theory prior to trial was set forth in his second expert report as follows:[5]

REDACTED

3 "Pls. Br." refers to Plaintiffs' Answering Brief in Opposition to Defendants' Motion to Strike Dr. Raskind's Trial Testimony on Enablement.

4 Plaintiffs' reliance on *Hill v. Reederi*, 435 F.3d 404, 423 (3d Cir. 2006) and *Johnson v. H.K. Webster, Inc.*, 775 F.2d 1,8 (1st Cir. 1985) to show that a recess should have been requested to investigate "surprise" testimony is misplaced because the Court's guidelines are very clear on the procedure to be followed in circumstances like these.

REDACTED

REDACTED

As can be seen from these two paragraphs, Dr. Raskind's expert reports is completely devoid of any discussion of the "nicotinic receptor theory."

REDACTED

See Northpoint Tech. v. MDS Am., 413 F.3d 1301, 1310 (Fed. Cir. 2005).

It is quite a stretch of the imagination to claim that paragraph 55 somehow discloses

Plaintiffs' nicotinic receptor theory. Paragraph 55 does not mention Plaintiffs' enablement theory based on the nicotinic receptors. Nor does paragraph 55 "connect" the '318 patent's description of galantamine properties disclosed in the prior art (in col. 1) with the animal testing (in col. 2) because the prior art discussed in the '318 patent fails to mention the nicotinic receptor theory. This was reiterated at trial. (Raskind at 1196-97).

Plaintiffs' reliance on paragraphs 45-46 of Dr. Raskind's second expert report (Pls. Br. at 4) is misplaced because those paragraphs also fail to mention the nicotinic receptor theory. Similarly, none of Dr. Raskind's deposition testimony that Plaintiffs cite (Pls. Br. at 4-6) discuss the nicotinic receptor theory.[6] Dr. Raskind's discussion of the animal lesion model in the '318 patent and the neuroendocrine system are insufficient to establish that the nicotinic receptor theory enables the '318 patent.

Realizing the absolute lack of any discussion of the nicotinic theory in his expert report, Plaintiffs attempt to rely on Dr. Raskind's deposition testimony to save his undisclosed opinion. However, this Court's rules make very clear that an expert's testimony is limited to his expert report, not his deposition testimony. Nonetheless, none of the reports and deposition testimony

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[6] Other courts are in accord with this Court's rules that even if Dr. Raskind did testify that the '318 patent is enabled due to the nicotinic receptor theory during his deposition, which he did not, that would not excuse his failure to mention the same in his expert reports. *See Forest Labs, Inc. v. Ivax Pharma, Inc.*, 237 F.R.D. 106, 113-14 (D. Del. 2006) (court sustained objections to expert's testimony which were not discussed in his report stating: "Dr. Gibbons should not have offered his opinions regarding how the FDA would have treated the violation because this was not included in his expert report. Although Dr. Gibbons did address the FDA issue during his deposition, that does not serve to place his trial testimony within the scope of his expert report."); *Takeda Chemical Indus., Ltd. v. Mylan Labs., Inc.*, 2006 WL 44053, *2 (S.D.N.Y. Jan. 9, 2006) (court granted a motion to strike opinions from an expert's affidavit that were not disclosed in the expert's report stating: "Discussion of a topic at a deposition is not a substitute for an expert report, ... Without a timely produced expert report, served sufficiently in advance of a deposition so that the adversary can effectively use the services of its own expert to prepare for a deposition, the adversary does not have an adequate opportunity, at the deposition, to test the expert's opinions and qualifications to assert those opinions.").

of Plaintiffs' other expert witnesses that Plaintiffs cited (*see* Pls. Br. at 5-6 at nn. 4-5 and p. 7) discuss the nicotinic receptor theory or that the '318 patent is enabled because of the nicotinic receptor theory. Even if they had, that does not cure the deficiency in Dr. Raskind's expert report.

Like Dr. Raskind's expert report, the two column '318 patent does not disclose the nicotinic receptor theory, as confirmed by the Court:

> There have been so much scientific literature thrown at me and so much language thrown at me, that it, from the description of Alzheimer's disease in the first place characterized by both loss of memory and this attention aspect that was mentioned by Dr. Davis ***to the fact that the nicotinic receptors play a role somehow in enhancing attention***, and then the whole mechanism of action of galanthamine and ***how it works on the nicotine receptors***, so I have a basic understanding of what's going on here.
>
> But my observation is this: With all of this going on, it is surprising to me that the patent itself says so little about any of this and I don't know where that leaves me, but I have to say when I look at the mountain of information you've given me and I look at the facts that ***the patent says very little other than use, try, galanthamine, it leaves me – I feel like there's something missing***. (Emphasis added.)

(Trial Tr. at 1148:13 to 1149:6). Indeed, Dr. Raskind confirmed during cross-examination that the '318 patent fails to mention nicotinic receptors:

> Q. She [Dr. Davis] doesn't say, my insight is that this [galantamine] will work in the nicotinic receptor and the nicotinic receptor is what we should be focusing on. You will not find those words in that ['318] patent?
>
> A. No.

(Trial Tr. at 1212:17-21).

As explained in Defendants' Joint Opening Post-Trial Brief (at 44) and at trial none of the prior art references cited in the '318 patent discloses the nicotinic receptor theory. Further, Dr. Davis never articulated her nicotinic receptor theory to the PTO in response to the

obviousness rejection. Dr. Davis never published articles articulating the nicotinic receptor theory. She also never mentioned this alleged unique galantamine nicotinic receptor theory in letters to potential licensees. (*See id.* at 47-48). Notably, the findings from the animal cholinergic lesioning model, which was completed after the '318 patent was issued, never based its significance on galanthamine's purported effect on the nicotinic receptors. DX 31 at 141. Dr. Raskind nor Dr. Davis denied any of this at trial.

On cross examination, it became even clearer that a person of ordinary skill would not agree that Dr. Raskind's nicotinic receptor theory was disclosed in the '318 patent. Dr. Raskind contradicts his own testimony that a person of ordinary skill in the art would understand the reference to Cozanitis in Column 1 Line 11 to 21 as disclosing that galanthamine was enhancing central nicotinic function. Raskind 1181:2-7. He conceded that a person of ordinary skill would have been forced to speculate as to whether the rise in cortisol level was attributed to a rise in diurnal cortisol level (which are muscarinic) or basal cortisol levels (which are nicotinic). Raskind Tr. at 1201:11-1202:9. Dr. Raskind never disputed that when given in small doses, "atropine does not always block the muscarinic receptors." Raskind Tr. at 1201:11-1202:9. Additionally, Dr. Raskind acknowledged that Cozanitis failed to provide "any indication in this paragraph anywhere what the dose of atropine was" used. *Id.* Accordingly, a person of skill in the art would have been left to guess as to "whether atropine was blocking the muscarinic receptor or having a peripheral effect." *Id.* Dr. Raskind's nicotinic receptor theory clearly attempted to create a definitive interpretation of the prior art where there was none.

C. Defendants were Unduly Surprised and Prejudiced by Dr. Raskind's Nicotinic Receptor Theory

Not that it is an element of the Court's rules, contrary to Plaintiffs' assertions (Pls. Br. at 7-8), Defendants were surprised and prejudiced by Dr. Raskind's enablement theory based on

nicotinic receptors presented for the first time at trial. Dr. Raskind's expert report was silent on the nicotinic receptor theory as it relates to enablement. As a result, there was no need to for Defendants' experts to rebut the nicotinic receptor theory as it relates to enablement in their expert reports. Consequently, at trial Defendants' experts did not opine with respect to the nicotinic receptor theory as it relates to enablement. After Defendants rested, Dr. Raskind presented for the first time his nicotinic receptor theory as it relates to enablement. This Court has excluded expert reports and supplements thereto when it does not give a party adequate time to respond.[7] *See Cuffee v. Dover Wipes Co.*, 334 F. Supp. 2d 565, 572 (D. Del. 2004) (J. Robinson) (excluding expert reports submitted too close to trial because "it would prejudice the defendants to include the reports because it would leave them little over a month to contact experts and get reports to counter the conclusions drawn by plaintiff's experts"); *Praxair, Inc. v. ATMI, Inc.*, 231 F.R.D. 457 (D. Del. 2005) (J. Robinson). Certainly if an expert's opinion in an expert report submitted before a month before trial was excluded, then an expert's opinion disclosed for the first time at trial should be excluded.

A new round of expert reports and depositions would have to occur before any new trial, and as stated in Defendants' Joint Opening Post-trial Brief at n. 31, if the Court finds that Dr. Raskind's trial testimony went beyond the scope of his expert reports, Defendants do **not** seek a new trial because of the quickly approaching '318 patent expiration date of December 2008. Retrying the case and getting through the appeals process before the patent expires (forgetting about any six month exclusivity that Defendants would be entitled to if victorious) would be virtually impossible. Even if Plaintiffs were forced to pay the costs of a new trial, this would be a paltry sum compared to the continuation of an ill-gotten monopoly.

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[7] At trial, Defendants presented their case-in-chief first because they stipulated to infringement and had the burden of proving invalidity of the '318 patent. As a result, Defendants were further prejudiced by not being able to address the nicotinic receptor theory as it relates to enablement as part of their case-in-chief.

Rather, Defendants believe that the appropriate sanction would be to strike Dr. Raskind's trial testimony on enablement. Plaintiffs did not object to this type of remedy in their Brief and it is an appropriate sanction for experts testifying beyond the scope of his/her expert report. *Advanced Medical Optics, Inc. v. Alcon Inc.*, 2005 WL 782809, * 5 and *11 (D. Del. April 7, 2005) (excluding experts' testimony on patent infringement and commercial success because opinions on those issues were not disclosed in the expert reports); *Air Turbine Technology, Inc. v. Atlas Copco AB*, 410 F.3d 701, 713 (Fed. Cir. 2005) (affirming district court's exclusion of expert testimony on issue not disclosed in the expert report).

In *Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 2005 WL 3525681 (D. Del. Dec. 22, 2005) (a patent case), the Court allowed testimony of an expert and reserved ruling on plaintiff's objection until later, noting, "[i]f it's not fairly noticed in the report, it gets excluded; if it's in the report, the objection gets overruled." *Id.* at *2. The Court reviewed the expert's report and found, "no mention of alleged impurities of racemic atorvastatin lactone compounds or the use of NMR to measure the impurity content of compounds." *Id.* Accordingly, the court excluded all of the expert's testimony pertaining to those subjects. *Id.* Likewise, Dr. Raskind's enablement testimony based on the nicotinic receptor theory should be excluded because it was not disclosed in his expert reports.

The contention that striking Dr. Raskind's enablement testimony "is an extreme sanction, not imposed absent a showing of willful deception and flagrant disregard of a Court Order by the proponent of the evidence" (Pls. Br. at 3, n. 3), is belied by this Courts rules and relevant case law. Nowhere does the Court's rules require such a showing. The cases that Plaintiffs cite for this proposition rely on cases that pre-date the 1993 amendments to Fed.R.Civ.P. 26 (formalizing

expert disclosure requirements) and Fed.R.Civ.P. 37 (regarding automatic sanctions).[8,]

Under the 1993 amendments, Fed.R.Civ.P. 37 provides that a party who, without substantial justification, fails to comply with the Fed.R.Civ.P. 26(a) expert disclosure requirements, is not, unless such failure is harmless, permitted to use such evidence at trial. This sanction is "automatic." Advisory Committee Notes to the 1993 Amendments to Fed.R.Civ.P. 37(c)(1). Plaintiffs have not provided any "substantial justification as to why their enablement theory was not timely disclosed in Dr. Raskind's expert reports. Nor is such an untimely disclosure "harmless" because Defendants were prejudiced, as explained below. Both Fed.R.Civ.P. 37 and the Court's guidelines provide that expert testimony during trial cannot go beyond the scope of his/her expert report.[9]

III. CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court strike Dr. Raskind's trial testimony as it relates to the enablement of the '318 patent.

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[8] Although Plaintiffs cite *Tracinda Corp. v. DaimlerChrysler AG*, 362 F. Supp. 2d 487 (D. Del. 2005), which post-dates the 1993 amendments to Fed.R.Civ.P. 26 and 37, *Tracinda* relies on *Myers v. Pennypack Woods Home Ownership Ass'n*, 599 F.2d 894 (3d Cir. 1977) which pre-dates the 1993 amendments.

[9] The Federal Rules of Civil Procedure allow for courts to set their own deadlines and rules. For example, Fed.R.Civ.P. 26(a)(2)(C) provides for the timing of expert witness disclosures "[i]n the absence of other directions from the court."

Respectfully submitted,

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